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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/476,253	12/30/1999	JOHN W. WATSON	PC9731A	7551

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EXAMINER
DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
1614	22

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/476,253	WATSON ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *3-6,12-15,21-24 and 32-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7-11,16-20,25-31 and 36-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Notice To Comply . . .

DETAILED ACTION

1. The request filed on May 6, 2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/476, 253 is acceptable and a CPA has been established. An action on the CPA follows.

The following is responsive to the preliminary amendment received May 6, 2003. Claims 40 and 41 have been previously cancelled in the amendment received June 18, 2002.

Claims 1-39 are currently pending.

Since, the instant application is a CPA of prior application 09476,253, the previous restriction/election mailed July 5, 2001 stands.

Information Disclosure Statement

Applicant's Information Disclosure Statements received March 13, 2000 and June 18, 2002 have been previously considered. Since Applicant has already received a copy of the 1449's, no copies will be submitted with this office action.

Priority

The amendment to the specification adding Applicant's claim for priority to provisional application 60/114,217 has been entered.

Specification

2. The abstract of the disclosure is objected to because the abstract is not limited to a single paragraph. Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc. Correction is required. See MPEP § 608.01(b).

Sequence Listing

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825). Please see claim 29.

Applicant is given THREE MONTHS from the mailing date of this communication within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Claim Objections

3. Claims 1-39 are objected to because of the following informalities: throughout claims 1-39 there are numerous Markush phrases presented as "selected from the group consisting essentially of...". This is improper Markush terminology. The phrases should read --selected from the group consisting of .....and....--. Please see MPEP 2173.05(h) Appropriate correction is required. Moreover, in claim 30, which depends from method claim 1, it appears as if Applicant is referring to claim 1 for the sole purpose of relying on the defined structures of Formula (1A) or Formula (1B). However, claim 30 is an independent pharmaceutical composition claim which should not depend from a method claim.

Claim Rejections - 35 USC § 112

4. Claims 11, 16-20, 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 19 are vague and indefinite because the metes and bounds of the patent protection desired is unclear. Claim 11 as well as claim 19 depend from claim 1 which recites a method for treating or preventing stasis in the stomach. However, claims 11 and 19 appear to be drawn to distinct methods of treating gastrointestinal disorders independent of whether stasis resulting from hypomotility is involved. In other words, it is not clear if claim 11 and 19 serve to further limit the scope of claim 1 by reciting gastrointestinal disorders in which the undesirable stasis occurs or whether claims 11 and 19 refer to claim 1 solely for definition of the structures recited in claim 1. Further clarification is respectfully requested.

For purposes of this office action, however, claims 11 and 19 will be interpreted as being drawn to distinct methods of treating gastrointestinal disorders independent of whether stasis resulting from hypomotility is involved.

In claim 19, line 5, the term "morphine-like" renders the claim vague and indefinite because the resulting claim(s) include(s) elements not actually disclosed (those encompassed by "like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 30-31, 36-39 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/42174 ('174) (already of record).

WO '174 discloses pharmaceutical compositions for administration to humans containing effective amounts (.1-1000 mg; .1-10 mg; .1-25 mg/kg; .3-5mg/kg, see Applicant's specification page 58) of the compounds embraced by Formula (I), with a preferred compound being Cis-4-Cyano-4-(1-(cyclohexyl-3-ethyl)-1H-indazol-6-yl)-cyclohexanecarboxylic acid. Please see page 9, lines 8-9; page 10, lines 10-29; page 24, lines 26 to page 25, line 10. WO '174 discloses that said compound is a PDE Type IV inhibitor. Please see page 10, lines 1-9.

Concerning the intended use of the compositions to treat or prevent stasis on the stomach, it is respectfully submitted that the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this case, the disclosed pharmaceutical compositions containing effective amounts disclosed/claimed by Applicant of the elected species would be capable of treating or preventing stasis in the stomach.

7. Claims 11, 16-20, 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/42174 ('174) (already of record).

WO '174 discloses methods of treating various gastrointestinal disorders such as Crohn's disease, ulcerative colitis, inflammatory bowel disease, wherein the methods comprise

administering pharmaceutical compositions containing effective amounts (.1-1000 mg; .1-10 mg; .1-25 mg/kg; .3-5mg/kg, see Applicant's specification page 58) of the compounds embraced by Formula (I), with a preferred compound being Cis-4-Cyano-4-(1-(cyclohexyl-3-ethyl)-1H-indazol-6-yl)-cyclohexanecarboxylic acid. Please see page 9, lines 8-9; page 10, lines 10-29; page 24, lines 26-30. WO '174 discloses that said compound is a PDE Type IV inhibitor. Please see page 10, lines 1-9.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 2, 7-10, are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/42174 ('174) in view of Stief et al., 5,891,904 (already of record).

WO '174 discloses methods of treating various gastrointestinal disorders such as Crohn's disease, ulcerative colitis, inflammatory bowel disease, wherein the methods comprise administering pharmaceutical compositions containing effective amounts (.1-1000 mg; .1-10 mg; .1-25 mg/kg; .3-5mg/kg, see Applicant's specification page 58) of the compounds embraced by Formula (I), with a preferred compound being Cis-4-Cyano-4-(1-(cyclohexyl-3-ethyl)-1H-indazol-6-yl)-cyclohexanecarboxylic acid. Please see page 9, lines 8-9; page 10, lines 10-29; page 24, lines 26-30. WO '174 discloses that said compound is a PDE Type IV inhibitor. Please see page 10, lines 1-9.

WO '174 does not specifically disclose that the methods also treat stasis resulting from hypomotility in the stomach; however, the Examiner turns to the Stief et al. patent, which discloses the use of pharmaceutical compositions containing PDE IV inhibitors for modulating

the motility or peristalsis of the gastrointestinal tract. Stief et al. teach that motility and peristalsis of the gastrointestinal tract is influenced by the inhibition of PDE IV. PDE IV inhibitors may be used to treat irritable colon or stomach cramps. Please see col. 1, line 61 to col. 2, line 22.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of WO '174 to treat or prevent stasis in the stomach because Stief et al. disclose that PDE IV inhibitors are capable of modulating motility and peristalsis of the gastrointestinal tract. Therefore, one of ordinary skill in the art would reasonably expect the PDE IV inhibitors of WO '174 to modulate the motility and peristalsis of the gastrointestinal tract of the patients disclosed in WO '174.

11. Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '174 and Stief et al., supra as applied to claims 1, 2, 7-10 above, and further in view of Demopulos et al., 5,820,583 (already of record).

WO '174 and Stief et al. as applied above.

WO '174 and Stief et al. do not disclose combining a proteinaceous opioid analgesic such as DAMGO with the PDE IV inhibitors to treat the gastrointestinal disorders; however, the Examiner refers to Demopulos et al., which disclose that DAMGO is a known opioid analgesic which induces anti-nociceptive effects. Please see col. 20, lines 40-61.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of WO '174 and Stief to co-administer an opioid analgesic such as

DAMGO because one of ordinary skill in the art would reasonably expect DAMGO to relieve any pain or discomfort associated with irritable/inflammatory bowel disease, Crohn's disease or ulcerative colitis.

Conclusion

Claims 1, 2, 7-11, 16-20, 25-31, 36-39 are rejected.

Claims 3-6, 12-15, 21-24, 32-35 are withdrawn from consideration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

May 16, 2003

Cybille Delacroix-Muirheid
Patent Examiner Group 1600